

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sundaram Ravikumar

Group Art Unit: 3731

Serial No.: 10/647,408

Examiner: Dawson, Glenn K

Filed: August 25, 2003

Attorney Docket: ARV-003

Title: Removable Blood Vessel Occlusion Device

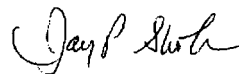
Honorable Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313

Sir:

Please substitute the enclosed Declaration for Patent Application and Power of Attorney to replace the original Declaration for Patent Application and Power of Attorney which was filed together with application no. 10/647,408 on August 25, 2003. This replacement Declaration is hereby submitted to (1) correct an inadvertent typographical error in the name of the sole inventor as set forth in the original Declaration; and (2) remove the priority claim information erroneously set forth in the original Declaration, in accordance with the amendment to the specification filed on December 20, 2006, a copy of which is attached hereto for your reference. Kindly send a Corrected Filing Receipt reflecting both of these changes to the undersigned attorney-of-record.

It is believed that no fee is due for this corrective filing. If any fee is due, please charge the fee to deposit account no. 07-1732.

Respectfully submitted,



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Acknowledgement Receipt

The USPTO has received your submission at **17:38:50** Eastern Time on **20-DEC-2006** by Deposit Account: 071732.

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eFiled Application Information

EFS ID	1389363
Application Number	10647408
Confirmation Number	2639
Title	Removable blood vessel occlusion device
First Named Inventor	Ravi Kumar
Customer Number or Correspondence Address	William L. Botjer PO Box 478 Center Moriches NY 11934 US 6318744826
Filed By	Jay Sbrolini
Attorney Docket Number	ARV-003
Filing Date	25-AUG-2003
Receipt Date	20-DEC-2006
Application Type	Utility

Application Details

Submitted Files	Page Count	Document Description	File Size	Warnings
AR1-ARV-003.pdf	12	Amendment - After Non-Final Rejection	117153 bytes	◆ PASS
fee-info.pdf	2	Fee Worksheet (PTO-06)	8121 bytes	◆ PASS

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing

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Applicant: Ravi Kumar

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Title: Removable Blood Vessel Occlusion Device

Honorable Commissioner for Patents
Alexandria, VA 22313

PREVIOUSLY FILED
ON DEC. 20, 2006

Sir:

PETITION FOR THREE MONTH EXTENSION OF TIME TO REPLY

The applicant hereby petitions the Commissioner for Patents for a three month extension of time to reply to an Office Action dated June 20, 2006. With the extension of time, the time for reply is extended to December 20, 2006 making this reply timely in nature. In the amendment presented herein, two additional dependent claims have been added. No additional claim fee is due. Please charge the \$510 small entity fee for the three month extension and any additional fee to deposit account no. 07-1732.

An Amendment to the Specification is found starting at page 2 hereof.

A Statement of the Claims (Amendment) is found starting on page 3 hereof.

Remarks are found starting on page 9 hereof.

AMENDMENT TO THE SPECIFICATION

On page 1, amend the paragraph beginning at line 4 as follows:

-- This application is related to ~~a continuation in part of~~ U.S. Patent Application
No. 10/086,745 filed March 1, 2002.

--.

STATEMENT OF THE CLAIMS

1. (currently amended) A plug for occluding a blood vessel having a severed end and a lumen extending therefrom, the plug comprising:

a first tapered body portion[[,]] having a diameter smaller than that of the lumen of the blood vessel;

a second disc-shaped ~~hollow-resilient~~ body portion depending from attached to the first ~~tapered~~ body portion, the diameter of the second ~~disc-shaped~~ body portion being larger than the diameter of the first ~~tapered~~ body portion and being larger than the diameter of the lumen of the blood vessel, wherein when the first and second body portions are inserted axially into the lumen of the blood vessel adjacent its severed end the wall of the lumen of the blood vessel expands and grasps the second body portion thereof and said plug thereby occludes blood flow through the lumen and out the severed end of the blood vessel; and

means operably coupled to attached to the inner part of the second disc-shaped body portion, the means permitting a user to effect a change in the diameter of the second ~~disc-shaped hollow~~ body portion to enable the removal of the plug from the severed end of the occluded blood vessel.

2. (currently amended) The occluding plug as claimed in claim 1, wherein: further including

the means causing the change in diameter of the second body portion includes a third cylindrical body portion depending from the second attached to the disc-shaped

~~body portion, said third cylindrical body providing access to the means for causing the change in diameter of the second disc shaped hollow body, and a filament attached to the third body portion.~~

3. (currently amended) The occluding plug as claimed in claim 1 2, wherein:

~~the third body portion is cylindrical means causing the change in diameter of the disc shaped body comprise a filament attached to the inner circumference of the disc shaped body.~~

4. (currently amended) The occluding plug as claimed in claim 3 2, wherein:

~~further including a third cylindrical body attached to the disc shaped body, said third cylindrical body portion has at least one including an aperture for securing the filament thereto to provide access to the means for causing the change in diameter of the second disc shaped hollow body.~~

5. (currently amended) The occluding plug as claimed in claim 1, wherein:

~~said first body portion has further including a rounded nosepiece attached to said first body.~~

6. (currently amended) The occluding plug as claimed in claim 1, wherein:

the plug is constructed from the group consisting of silicone, polyurethane and polyisobutylene-based polymers.

7. (currently amended) The occluding plug as claimed in claim 1, further including:

a longitudinal pilot hole defined by said plug and capable of ~~for~~ receiving a insertion device.

8. (currently amended) The occluding plug as claimed in claim 7, further including:

an insertion device capable of ~~for~~ inserting the occluding plug axially into the lumen of the blood vessel adjacent its severed end, the insertion device having a needle that is operably disposed within the pilot hole of the occluding plug, a tubular needle-guard surrounding the needle, the tubular needle guard fitting into the pilot hole of the plug, a spring connected to the needle to propel the needle outwards and to thereby urge the plug into the vessel, and a lever operable to compress and decompress the spring.

9. (currently amended) The occluding plug as claimed in claim ~~1~~ 7, wherein:

said first body is tapered pilot hole is formed in said first, second and third body portions.

10. (currently amended) A kit ~~A plug for occluding a blood vessel~~ comprising:

the occluding plug of claim 7; and

a first body, having a largest diameter smaller than that of the blood vessel;

a second disc shaped hollow resilient second body attached to the first tapered body, the diameter of the second disc shaped body being larger than the diameter of the first tapered body and the diameter of the blood vessel so that upon insertion into a blood

~~vessel the disc shaped hollow resilient body will distend the blood vessel to hold the plug in place;~~

~~means attached to the inner part of the second disc shaped body, the means permitting a user to effect a change in the diameter of the second disc shaped hollow body to, enable the removal of the plug from the occluded blood vessel; and a third body portion attached to the disc shaped body, said third body providing access to the means for causing the change in diameter of the second disc shaped hollow body~~

an insertion device capable of inserting the occluding plug axially into the lumen of the blood vessel adjacent its severed end, the insertion device having a needle that is operably disposed within the pilot hole of the occluding plug.

11. (currently amended) The kit ~~occluding plug~~ as claimed in claim 10, wherein:

the means causing the change in diameter of the second disc shaped body portion of the occluding plug ~~comprise~~ includes a filament attached to the third body portion inner circumference of the disc shaped body, the filament causing the second body portion disc shaped body to collapse when pulled by a user to permit removal of the occluding plug from the severed end of the blood vessel.

12. (currently amended) The kit ~~occluding plug~~ as claimed in claim ~~10~~ 11, wherein:

said third body portion includes at least one aperture through which the filament extends.

13. (currently amended) The kit ~~occluding plug~~ as claimed in claim 10, wherein:

the first body portion of the occluding plug has further including a rounded
nosepiece ~~attached to said first body.~~

14. (currently amended) The kit occluding plug as claimed in claim 10, wherein:

the occluding plug is constructed from the group consisting of silicone,
polyurethane and polyisobutylene-based polymers.

15. (currently amended) The kit occluding plug as claimed in claim ~~4~~ 10, wherein:

said first body portion of said occluding plug is conical.

16. (currently amended) The kit occluding plug as claimed in claim 10, wherein:

said occluding plug includes a third body is cylindrical portion depending from
said second body portion.

17. (currently amend) The kit occluding plug as claimed in claim ~~10~~ 16, wherein: ~~further~~
~~including a longitudinal pilot hole for receiving a insertion device~~

said third body portion of said occluding plug is cylindrical.

18. (currently amended) The kit occluding plug as claimed in claim ~~17~~ further including
10, wherein:

said an insertion device for inserting the plug into the blood vessel, the insertion
device includes at least one of having a needle,

i) a tubular needle guard surrounding the needle, the tubular needle guard fitting into the pilot hole of the occluding plug,

ii) a spring connected to the needle to propel the needle outwards and to thereby urge the occluding plug into the lumen of the blood vessel adjacent its severed end, and

iii) a lever operable to propel the needle outwards and to thereby urge the occluding plug into the lumen of the blood vessel adjacent its severed end ~~compress and decompress the spring~~.

19. (new) The occluding plug as claimed in claim 17, wherein:

said pilot hole is formed in said first, second and third body portions.

20. (new) The kit according to claim 8, wherein:

the insertion device includes at least one of

i) a tubular needle guard surrounding the needle, the tubular needle guard fitting into the pilot hole of the occluding plug,

ii) a spring connected to the needle to propel the needle outwards and to thereby urge the occluding plug into the lumen of the blood vessel adjacent its severed end, and

iii) a lever operable to propel the needle outwards to thereby urge the occluding plug into the lumen of the blood vessel adjacent its severed end.

REMARKS

Applicant has amended the claims to address the objection to the drawings, the rejection of the claims under 35 USC §101 and the rejection of the claims under 35 USC §112. Applicant respectfully submits that these rejections are now moot.

Applicant respectfully traverses the Examiner's objection to the disclosure. As is described in lines 1-20 of page 10 of the present application, the plug is removed by folding or collapsing of the disc-shaped body portion 112 of the plug. This can be accomplished by pulling on the ends of a filament that is secured to a body portion 114 that depends from the disc-shaped body portion 112. Thus, the Examiner's objection to the disclosure is flawed and should be removed.

Claims 1-7 and 9-17 stand rejected under 35 USC 102(e) as being anticipated by Sepetka. Applicant has amended the claims to more particularly define over the cited prior art.

More particularly, claim 1 recites, *inter alia*,

... a second disc-shaped body portion depending from the first body portion, **the diameter of the second body** being larger than the diameter of the first body portion and **being larger than the diameter of the lumen of the blood vessel, wherein when the first and second body portions are inserted axially into the lumen of the blood vessel**

**adjacent its severed end the wall of the lumen of the blood vessel
expands and grasps the second body portion thereof and said plug
thereby occludes blood flow through the lumen and out the severed
end of the blood vessel**

Nowhere does Sepetka teach or suggest this feature.

The apparatus in Sepetka et al. includes an expandable device 4 (fiber mesh structure) which is delivered through vessel lumen(s) to an aneurysm and expanded therein to partially fill the aneurysm. The aneurysm is reduced in size so that expandable structure supports and reinforces the body and neck of the aneurysm wall (Fig. 6). The aneurysm is reduced in size by heating the aneurysm wall (by RF energy applied thereto by the device 4) or by chemical action. A sealant may be introduced into the aneurysm to seal it.

Importantly, there are significant differences between the occlusion plug of the present invention and the prior art. First, the prior art device of Sepetka is securely located in a different part of the vascular system than the claimed plug and the prior art device of Sepetka performs different functions than the claimed occlusion plug. More particularly, the claimed plug is positioned axially in the lumen of the blood vessel adjacent its severed end and held in place by the wall of the lumen of the blood vessel grasping the occlusion plug, and operates to block the flow of blood through the vessel lumen out the severed end of the blood vessel. In contrast, the expandable device of Sepetka is inserted into an aneurysm. **The aneurysm is not part of the vessel lumen; it**

is an enlargement of the vessel that protrudes radially outward like a balloon from the wall of the vessel. Therefore, the device of Sepetka does not block the flow of blood through the lumen. In fact, if it did, the patient might die.

Second, there are significant differences regarding how the prior art Sepetka device is secured in place as compared to the claimed occlusion plug. The claimed occlusion plug includes a **large diameter second body portion that is larger than the lumen diameter in its at rest state such that when pushed into the lumen, the lumen wall expands and grasps the second body portion.** In contrast, the expandable device 4 of Sepetka is maintained at a smaller diameter than the lumen of the vessel through which it travels. After expansion, it is maintained at a size that is smaller than the neck of aneurysm. The aneurysm is shrunk in size to fit around the device. Thus, the expandable device 4 is not gripped by the walls of an expanded lumen of a blood vessel, but by shrinking of the aneurysm wall.

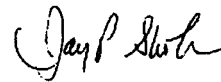
Because of these significant differences, Applicant respectfully submits that independent claim 1 as amended is patentable over the cited prior art. Similar arguments apply to independent claim 10.

Dependent claims 2-7, 9, and 11-17 and 19-20 are patentable over the cited prior art for those reasons advanced above with respect to independent claims 1 and 10 from which they respectively depend and for reciting additional features neither taught nor suggested by the cited prior art. For example, claim 11 is directed to a filament attached

to a third body portion depending from the second body portion, the filament causing the second body portion to collapse when pulled by a user to permit removal of the plug from the severed end of the blood vessel. Nowhere does the cited prior art teach or suggest this feature.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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December 20, 2006